Complete Summary

GUIDELINE TITLE

Sixth ACCP Consensus Conference on Antithrombotic Therapy.

BIBLIOGRAPHIC SOURCE(S)

Hirsh J, Dalen J, Guyatt G. The sixth (2000) ACCP guidelines for antithrombotic therapy for prevention and treatment of thrombosis. American College of Chest Physicians. Chest 2001 Jan;119(1 Suppl):1S-370S.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Thromboembolic disorders and conditions that predispose to thromboembolism, including the following:
  - Coronary artery disease
  - Acute myocardial infarction
  - Unstable angina
  - Ischemic stroke
  - Saphenous vein or internal mammary artery bypass grafts
  - Atrial fibrillation
  - Venous thromboembolism
  - Peripheral arterial occlusive disease
  - Valvular heart disease
  - Mechanical or biological prosthetic heart valves
  - Pregnancy
  - Percutaneous coronary interventions
  - Surgery (major general, gynecologic, and urologic surgery; lower extremity arthroplasty and hip fracture repair; neurosurgery)
  - Major trauma or spinal cord injury

        - Other conditions, including central catheters, endovascular stents, extra/corporeal membrane oxygenation, hemodialysis, continuous venovenous hemoperfusion
        - Other pediatric conditions, including congenital prothrombic disorders, Kawasaki's disease, Fontan's procedure, Blalock-Taussig shunts
    - Heparin induced thrombocytopenia with or without thrombosis

GUIDELINE CATEGORY

Management
Prevention
Treatment

CLINICAL SPECIALTY

Cardiology
Critical Care
Emergency Medicine
Family Practice
Internal Medicine
Obstetrics and Gynecology
Pediatrics
Pulmonary Medicine
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To present evidence-based clinical practice guidelines to assist clinicians in preventing, managing, or effectively treating thrombotic disorders in their patients
- To enhance the quality of patient care
- To assist clinicians in providing safe and effective antithrombotic therapy to their patients
- To reflect a standard of practice in antithrombotic therapy
- To lead to further dialogue and to stimulate further studies in the important area of antithrombotic therapeutics

TARGET POPULATION

Adult and pediatric patients who are candidates for antithrombotic therapy

INTERVENTIONS AND PRACTICES CONSIDERED

1. Antithrombotic pharmacotherapy, including:
    - Heparin; mini-dose unfractionated heparin; moderate-dose unfractionated heparin; adjusted-dose unfractionated heparin; low-molecular-weight-heparin (dalteparin, enoxaparin, nadroparin,

tinzaparin, reviparin); adjusted-dose low-molecular-weight-heparin; low-dose unfractionated heparin; adjusted-dose heparin; low-dose heparin; heparinoids including danaparoid
    - Warfarin (Coumadin); adjusted-dose warfarin
    - Antiplatelet therapy, including aspirin and low-dose aspirin; thienopyridines (clopidogrel and ticlopidine); triflusal; dipyridamole; sulfinpyrazone; platelet glycoprotein IIb/IIIa receptor inhibitors (glycoprotein IIb/IIIa antagonists): abciximab; eptifibatide, tirofiban
    - Thrombolytic agents, including streptokinase; urokinase; tissue plasminogen activator; recombinant tissue plasminogen activator; anistreplase; tenecteplase; reteplase, alteplase
    - Other agents, hirudin, bivalirudin
    - Combination therapies, including: oral anticoagulant therapy in combination with a variety of antiplatelet therapies; aspirin therapy in combination with a variety of other antiplatelets agents, such as dipyridamole, clopidogrel, or ticlopidine; oral anticoagulant therapy in combination with heparin therapy; fibrinolytic therapy in combination with aspirin, heparin, or hirudin
    - Blood component therapy [administration of fresh frozen plasma; protein C concentrate; prothrombin complex; cryoprecipitate]
2. Nonpharmacologic interventions to prevent venous thromboembolism (early ambulation, elastic stockings, intermittent pneumatic compression; inferior vena cava filter placement)
3. Monitoring of laboratory values (anti-factor Xa levels, activated partial thromboplastin time, prothrombin time, international normalized ratio values, plasma heparin levels)
4. Therapy for heparin-induced thrombocytopenia including danaparoid sodium (Orgaran); recombinant hirudin (lepirudin); argatroban (Novastan); warfarin (Coumadin)

MAJOR OUTCOMES CONSIDERED

The effects of antithrombotic therapy, used in treating a variety of conditions, on:

- Rate of adverse events (e.g., ischemic stroke)
- Rate of complications (e.g., hemorrhage)
- Rate of and relative risk reduction for thromboembolic events
- Mortality
- Survival
- Rate and type of short- and long-term morbidities
- Short- and long-term costs
- Laboratory measurements (anti-Xa levels, activated partial prothrombin time levels, platelet counts)

The efficacy of various antithrombotic therapies in preventing thromboembolism, gauged by measures including quality-adjusted life expectancy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The participants reviewed information from an exhaustive review of the literature. Different topics (guideline sections) necessitated different literature searches.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The rating scheme framework captures the trade-off between benefits and risks (1 or 2) (see "Rating Scheme for the Strength of the Recommendations") and the methodologic quality of the underlying evidence (A, B, C+, or C).

Grades of evidence for antithrombotic agents:

1A
Methodological strength of supporting evidence: randomized controlled trials without important limitations

1B
Methodological strength of supporting evidence: randomized controlled trials with important limitations (inconsistent results, methodologic flaws*)

1C+
Methodological strength of supporting evidence: no randomized controlled trials, but randomized controlled trial results can be unequivocally extrapolated; or, overwhelming evidence from observational studies

1C
Methodological strength of supporting evidence: observation studies

2A
Methodological strength of supporting evidence: randomized controlled trials without important limitations

2B
Methodological strength of supporting evidence: randomized controlled trials with important limitations (inconsistent results, methodologic flaws*)

2C
Methodological strength of supporting evidence: observational studies

* Such situations include randomized controlled trials with lack of blinding, and subjective outcomes, in which the risk of bias in measurement of outcomes is high; and randomized controlled trials with large loss to follow-up.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The strength of any recommendation depends on two factors: the trade-off between benefits and risks, and the strength of the methodology that leads to estimates of the treatment effect. The rating scheme used for this guideline captures these factors. The guideline developers grade the trade-off between benefits and risks in two categories: (1) the trade-off is clear enough that most patients, despite differences in values, would make the same choice; and (2) the trade-off is less clear, and each patient's values will likely lead to different choices.

When randomized trials provide precise estimates suggesting large treatment effects, and risks and costs of therapy are small, treatment for average patients with compatible values and preferences can be confidently recommended.

If the balance between benefits and risks is uncertain, methodologically rigorous studies providing grade A evidence and recommendations may still be weak (grade 2). Uncertainty may come from less precise estimates of benefit, harm, or costs, or from small effect sizes.

There is an independent impact of validity/consistency and the balance of positive and negative impacts of treatment on the strength of recommendations. In situations when there is doubt about the value of the trade-off, any recommendation will be weaker, moving from grade 1 to grade 2.

Grade 1 recommendations can only be made when there are precise estimates of both benefit and harm, and the balance between the two clearly favors recommending or not recommending the intervention for the average patient with compatible values and preferences. Table 2 of the original guideline document summarizes how a number of factors can reduce the strength of a

recommendation, moving it from grade 1 to grade 2. Uncertainty about a recommendation to treat may be introduced if the target event that is trying to be prevented is less important (confident recommendations are more likely to be made to prevent death or stroke than asymptomatic deep venous thrombosis); if the magnitude of risk reduction in the overall group is small; if the risk is low in a particular subgroup of patients; if the estimate of the treatment effect, reflected in a wide confidence interval (CI) around the effect, is imprecise; if there is substantial potential harm associated with therapy; or if there is an expectation for a wide divergence in values even among average or typical patients. Higher costs would also lead to weaker recommendations to treat.

The more balanced the trade-off between benefits and risks, the greater the influence of individual patient values in decision making. If they understand the benefits and risks, virtually all patients will take aspirin after myocardial infarction or will comply with prophylaxis to reduce thromboembolism after hip replacement. Thus, one way of thinking about a grade 1 recommendation is that variability in patient values or individual physician values is unlikely to influence treatment choice in average or typical patients.

When the trade-off between benefits and risks is less clear, individual patient values will influence treatment decisions even among patients with average or typical preferences.

Grade 2 recommendations are those in which variation in patient values or individual physician values will often mandate different treatment choices, even among average or typical patients.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The rating scheme framework captures the trade-off between benefits and risks (1 or 2) and the methodologic quality of the underlying evidence (A, B, C+, or C) (see "Rating Scheme for the Strength of the Evidence").

Grades of recommendation for antithrombotic agents:

1A
Clarity of risk/benefit: risk/benefit clear
Implications: strong recommendation; can apply to most circumstances, without reservation

1B
Clarity of risk/benefit: risk/benefit clear
Implications: strong recommendation; likely to apply to most patients

1C+
Clarity of risk/benefit: risk/benefit clear
Implications: strong recommendation; can apply to most patients in most circumstances

1C
Clarity of risk/benefit: risk/benefit clear

Implications: intermediate-strength recommendation; may change when stronger evidence available

2A
Clarity of risk/benefit: risk/benefit unclear
Implications: intermediate strength recommendation; best action may differ, depending on circumstances or patients' societal values

2B
Clarity of risk/benefit: risk/benefit unclear
Implications: weak recommendation; alternative approaches likely to be better for some patients under some circumstances

2C
Clarity of risk/benefit: risk/benefit unclear
Implications: very weak recommendation; other alternatives may be equally reasonable

COST ANALYSIS

While the American College of Chest Physicians conference participants considered cost in deciding on the strength of recommendations, the paucity of rigorous cost-effective analyses and the wide variability of costs across jurisdictions led the guideline developers to take a conservative approach to cost issues. That is, cost considerations influenced the recommendations and the grades of those recommendations only when the gradient between alternatives was very large.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The initial guidelines were prepared by the chapter committee (the primary authors) and then reviewed separately by the Committee Co-Chairs and methodology experts and finally by the entire group of Consensus Guideline participants.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the American College of Chest Physicians: This record outlines the content of the Sixth American College of Chest Physicians Consensus Conference on Antithrombotic Therapy with links to NGC records on specific topics and text.

Antithrombotic Agents

- In coronary heart disease

- In ischemic stroke
- In patients with saphenous vein or internal mammary artery bypass grafts
- In atrial fibrillation
- For prevention of venous thromboembolism
- In treatment of venous thromboembolic disease
- In peripheral arterial occlusive disease
- In valvular heart disease
- In patients with mechanical or biological prosthetic heart valves
- In pregnant patients
- In pediatric patients

Intravenous Thrombolysis in Acute Myocardial Infarction

Use of Oral Anticoagulants

Evidence from randomized controlled trials continues to support the use of less-intense warfarin treatment for many indications. Within an international normalized ratio (INR) range of 2.0 to 3.0, the lower level generally is safer and equally effective. Recommended therapeutic ranges for the various indications remain unchanged (see table below). Recent studies do not support the use of fixed low-dose warfarin therapy in patients with acute myocardial infarction or atrial fibrillation.

Table. Recommended therapeutic range for oral anticoagulant therapy

INDICATION	INTERNATIONAL NORMALIZED RATIO (INR) RANGE
Prophylaxis of venous thrombosis (high-risk surgery)	2.0 to 3.0
Treatment of venous thrombosis	2.0 to 3.0
Treatment of pulmonary embolism	2.0 to 3.0
Prevention of systemic embolism	2.0 to 3.0
Tissue heart valves	2.0 to 3.0
Acute myocardial infarction (to prevent systemic embolism)*	2.0 to 3.0
Valvular heart disease	2.0 to 3.0
Mechanical prosthetic valves (high risk)	2.5 to 3.5
Bileaflet mechanical valve in aortic position	2.0 to 3.0

Certain patients with thrombosis and the antiphospholipid syndrome	> 2.0 to 3.0

*If oral anticoagulant therapy is elected to prevent recurrent myocardial infarction, an international normalized ratio of 2.5 to 3.5 is recommended, consistent with Food and Drug Administration recommendations.

Managing Oral Anticoagulant Therapy

New Anticoagulants

Anticoagulant strategies to inhibit thrombogenesis have focused on inhibiting thrombin, preventing thrombin generation, or blocking the initiation of coagulation. Thrombin inhibitors block thrombin activity; agents that target clotting enzymes higher in the coagulation pathways prevent thrombin generation. Coagulation factors targeted for inactivation include factor Xa, factor IXa, and the factor VIIa/tissue factor complex. Other approaches to attenuating thrombogenesis include enhancing endogenous anticoagulant pathways or promoting fibrinolysis.

This table lists new anticoagulants in advanced stages of clinical development.

TARGET	DRUG	ROUTE	STATUS	INDICATION
VIIa/tissue factor	Tissue factor pathway inhibitor	Intravenous	Phase III	Sepsis
	Nematode anticoagulant peptide c2	Subcutaneous	Phase II	Thromboprophyla (elective knee arthroplasty)
Va/VIIIa	Activated protein C	Intravenous	Phase III	Sepsis
Xa	Pentasaccharide	Subcutaneous	Phase III	Thromboprophyla (elective hip or knee arthroplasty hip fracture)
				Venous thromboembolism
	DX-9065a	Intravenous	Phase II	Unstable angina
Xa/thrombin	SNAC/heparin*	Oral	Phase II	Thromboprophyla (elective hip or knee arthroplasty
Thrombin	Hirudin	Intravenous	Approved	Heparin-induced

				thrombocytopeni
			Under review	Unstable angina; non-ST-elevation myocardial infarction
	Bivalirudin	Intravenous	Approved	Alternative to heparin for coronary angioplasty
	Argatroban	Intravenous	Approved	Heparin-induced thrombocytopeni
	H376/95	Oral	Phase III	Thromboprophyla (elective hip or knee arthroplasty
			Phase II	Alternative to warfarin in atrial fibrillation

*Sodium N-(8[2-hydroxybenzoyl]amino) caprylate

Hemorrhagic Complications of Anticoagulant Treatment

Oral anticoagulants: the major determinants of bleeding from the use of oral anticoagulants are the intensity of the anticoagulant effect, characteristics of the patient, and length of therapy. The risk for bleeding appears to be reduced with the use of low-intensity oral anticoagulant therapy (goal international normalized ratio 2.5; range 2.0 to 3.0). Lower-intensity regimens (international normalized ratio <2.0) are associated with further reduction in major bleeding episodes. In selecting therapy, the potential decrease in risk for thromboembolism must be balanced against the potential increase in risk for bleeding.

Heparins: in patients with acute venous thromboembolism, the risk for bleeding associated with intravenous heparin is <3% in recent trials, but appears to increase if higher dosages of heparin are used, and if the patient's age is >70 years. Use of low-molecular weight heparin, compared with standard heparin, is not associated with an increase in major bleeding episodes in patients with venous thromboembolism.

Use of standard heparin and low-molecular weight heparin is associated with an increase in major bleeding episodes in ischemic stroke, but not in ischemic coronary syndromes.

Use of Platelet-Active Drugs

Studies continue to confirm the effectiveness of platelet-active drugs in treating and preventing thrombotic disorders. Minimum effective doses of aspirin in the following clinical situations can be found in the original guideline document: men at cardiovascular risk, hypertension, stable angina, unstable angina, acute myocardial infarction, transient ischemic attack and ischemic stroke, severe carotid artery stenosis, and acute ischemic stroke. Clopidogrel, ticlopidine, dipyridamole, and intravenous glycoprotein IIb/III antagonists can be substituted for or combined with aspirin, in some conditions.

Use of Heparin and Low-Molecular Weight Heparin

Antithrombotic Therapy in Patients Undergoing Percutaneous Coronary Intervention

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

All recommendations in the document are based upon careful review and grading of evidence in studies published in peer-reviewed journals. The type of supporting evidence is identified for each recommendation (refer to the links to individual National Guideline Clearinghouse summaries provided in the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Guidelines for antithrombotic therapy may help physicians prevent, manage, and treat thromboembolic disorders and their complications in order to improve patient outcomes, while reducing the risk of adverse effects of therapy (such as bleeding) as well as unnecessary cost.

For more detailed information, refer to the links to individual National Guideline Clearinghouse summaries provided in the "Major Recommendations" field.

Subgroups Most Likely to Benefit:

Refer to the links to individual National Guideline Clearinghouse summaries provided in the "Major Recommendations" field.

POTENTIAL HARMS

The major risk associated with anticoagulation (from warfarin, heparin, or antiplatelet drugs) and thrombolytic therapy is bleeding. Occasionally, serious consequences occur, such as intracerebral hemorrhage or even death.

Detailed information about specific antithrombotic agents is provided in individual summaries. Refer to the links to individual National Guideline Clearinghouse summaries provided in the "Major Recommendations" field.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Interpreting the Recommendations

The authors of these guidelines offer recommendations that should not be construed as dictates by the readers, including clinicians, third-party payers, institutional review committees, and courts. In general, anything other than a 1A recommendation indicates that the chapter authors acknowledge that other interpretations of the evidence and other clinical policies may be reasonable and appropriate. Even grade 1A recommendations will not apply to all circumstances and all patients. For instance, the guideline developers have been conservative in their considerations of cost, and have seldom downgraded recommendations from 1 to 2 on the basis of expense. As a result, in jurisdictions in which resource constraints are severe, alternative allocations may serve the health of the public far more than some of the interventions that the authors designate grade 1A. This will likely be true for all less-industrialized countries. However, a weak recommendation (2C) that reduces resource consumption may be more strongly indicated in less-industrialized countries.

Similarly, following grade 1A recommendations will at times not serve the best interests of patients with atypical values or preferences. For instance, consider patients who find anticoagulant therapy extremely aversive, either because it interferes with their lifestyle (prevents participation in contact sports, for instance) or because of the need for monitoring. For such patients, clinicians may reasonably conclude that following some grade 1A recommendations for anticoagulation will be a mistake. The same may be true for patients with particular comorbidities (such as a recent gastrointestinal bleed or a balance disorder with repeated falls) or other special circumstances (such as very advanced age).

The guideline developers trust that these observations convey their acknowledgment that no guidelines or recommendations can take into account the often compelling idiosyncrasies of individual clinical circumstances. No clinician and no one charged with evaluating the actions of a clinician should attempt to apply their recommendations in a rote or blanket fashion.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Hirsh J, Dalen J, Guyatt G. The sixth (2000) ACCP guidelines for antithrombotic therapy for prevention and treatment of thrombosis. American College of Chest Physicians. Chest 2001 Jan;119(1 Suppl):1S-370S.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jan

GUIDELINE DEVELOPER(S)

American College of Chest Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

Funding was supplied by DuPont Pharmaceuticals.

GUIDELINE COMMITTEE

American College of Chest Physicians Consensus Panel on Antithrombotic Therapy

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline is an updated version of the 1998 Fifth ACCP consensus conference on antithrombotic therapy (Chest 1998 Nov;114[5 Suppl]:439S-769S).

GUIDELINE AVAILABILITY

Electronic copies of the updated guideline: Available from the Chest - The Cardiopulmonary and Critical Care Journal Web site.

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Sixth ACCP Consensus Conference on Antithrombotic Therapy (2001): summary recommendations. Northbrook, IL: ACCP, 2001. (Quick reference guide for clinicians).

Electronic copies: Available from the American College of Chest Physicians Web site. (HTML, Portable Document Format [PDF], and downloadable files intended for use with Palm OS compatible devices are available.)

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348, or by calling 1 (800) 343-2227.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on August 26, 2001. The information was verified by the guideline developer on September 24, 2001.

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